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10/018,470	11/21/2002	Claire Marie Fraser	CHIR-0319	2853
7500 11/12/2009 Chiron Corporation Intellectual Property R440			EXAMINER	
			NEGIN, RUSSELL SCOTT	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/018,470 FRASER ET AL. Office Action Summary Examiner Art Unit RUSSELL S. NEGIN 1631 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 02 July 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.2.4.26 and 83-85 is/are pending in the application. 4a) Of the above claim(s) 4 and 26 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1,2 and 83-85 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 21 November 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 8/3/09

Notice of Draftsperson's Patent Drawing Review (PTO-948)
Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Comments

Applicants' amendments and request for reconsideration in the communication filed on 2 July 2009 are acknowledged and the amendments are entered.

Claims 4 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 10 June 2005.

Claims 1, 2, 4, 26 and 83-85 are pending in this application, and claims 1-2 and 83-85 are examined in this Office action.

Withdrawn Rejection

The rejection of claim 85 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of arguments filed on pages 4-5 of the Remarks.

Information disclosure statement

The information disclosure statement filed on 3 August 2009 has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejection is newly applied:

Claims 1-2 and 83-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While the first step of independent claim 1 recites "providing a computer database comprising the *N. meningitidis* serogroup B strain MC58 genome sequence of SEQ ID NO:1," this specific SEQ IS NO has no role in the remaining steps of the claims. Consequently, while the database analyzes a sequence, it is not clear from the steps of the claims what action to take on this specific sequence data. For example, while the second step searches for ORFs, the third step identifies amino acid encoded by the ORFs, and the fourth and fifth steps output and produce these amino acids, respectively, SEQ ID NO:1 has no specific function in these remaining steps.

Claim Rejections - 35 USC § 103

The following rejection is reiterated:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribot et al. [WIPO WO 98/17805; published 30 April 1998; on IDS of 9 September 2002] in view of Chee et al. [US Patent 5,795,716; issued 18 August 1998; filed 21 October 1994].

The claims are drawn to a method for identifying an amino acid sequence from the *N. meningitidis* serogroup B strain MC58 genome. This method comprises the step of providing a computer database comprising the N. meningitides serogroup B strain MC58 genome sequence of SEQ ID NO:1. The method also comprises searching for putative open reading frames or protein-coding sequence within the computer database. The method also comprises identifying an amino acid sequence corresponding to the searched putative open reading frame or protein coding sequences. The method also comprises outputting the identified amino acid sequence to a user display or storing the identified amino acid sequence to a computer readable media. The method also comprises producing a protein comprising the identified amino acid sequence.

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Claim 2 further comprises searching the computer database containing SEQ ID NO:1 for an initiation codon; and searching for an in-frame termination codon downstream of the initiation codon.

Claim 83 is further limiting comprising outputting the identified amino acid sequence to a user display.

Claim 84 is further limiting comprising storing the identified amino acid sequence to a computer storage medium.

Claim 85 is further limiting wherein the putative open reading frame does not consist of one or more of NMB0427. NMB 0428. NMB0429, and NMB0430.

Ribot et al. disclose a method of automated DNA sequence analysis of PCR fragments using a dye terminator reaction method (page 57, lines 2-7) for identifying serogroup B amino acid sequences comprising the step of computer assisted analysis (page 57, lines 5-7) for putative open reading frames (see Figure 1 of Ribot et al. and SEQ ID NO 6 and SEQ ID NO 3 of Ribot et al.) or coding an amino acid sequence with *N. meningitidis* nucleotide sequence (SEQ ID NO: 1 of Ribot et al.). As shown in Ribot et al., SEQ ID NO: 1 of Ribot et al. comprises the initiation codon (i.e. ATG, see SEQ ID NO:1 of Ribot et al., line 1, positions 16-18), an in frame termination codon (see SEQ ID NO:1 of Ribot et al., line 1, position 1100, and 1148). Ribot et al. discloses a method for searching ORFs or protein coding sequences of *Neisseria meningitidis* (Ribot et al., pages 57-59 expands on this analysis). Additionally, Figures 5-7 of Ribot et al. comprise a database of several SEQ ID NOs. These sequences are discussed on page 6, lines 20-30 of Ribot et al. with protein (i.e. amino acid) sequences assigned to the

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ORF. Additionally, the examples in Ribot et al. (pages 50-60) describe production of proteins associated with the ORFs.

It is noted that since instant claim 1 (of the instant application) recites "...genome sequence of SEQ ID NO:1," this limitation is assigned an interpretation such that any prior art that teaches a fragment of SEQ ID NO:1 meets this limitation (i.e. the entirety or 100% homology to this sequence is not required as currently recited). Additionally as claim 1 uses open language such that the computer database COMPRISES the genome sequence recited in SEQ ID NO:1, any full sequence with an overlapping fragment (i.e. the dinucleotide "TG" is in both instantly recited SEQ ID NO:1 and SEQ ID NO:1 of Ribot et al.) meets this sequence limitation in instant claim 1.

However, Ribot et al. does not discuss analysis of the genome sequence of instantly claimed SEQ ID NO. 1 in the computer storage medium or user display as recited in the instantly rejected claims.

The patent of Chee et al. discussed the computer-aided visualization and analysis system for sequence evaluation. Specifically, the system as illustrated in Figure 1 has a computer storage medium and a display device.

It would have been further obvious to someone of ordinary skill in the art at the time of the instant invention to modify the sequence database of Ribot et al. by use of the storage and visualization systems of Chee et al. wherein the motivation would have been that the storage and visualization of Chee et al. have the advantage of more conveniently viewing and recording data pertaining to computer visualization of sequences [i.e. see Figure 1 of Chee et al.]

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Response to Arguments:

Applicant's arguments filed 2 July 2009 have been fully considered but they are not persuasive. Applicant first argues that the amendments to instant claim 1 overcome the rejection of record. This argument is not persuasive because, as discussed above, the combination of Ribot et al. and Chee et al. teach or suggest all of the limitations of the instantly Rejected claims.

Applicant further argues that since there are differences between SEQ ID NO:1 of Ribot et al. and the SEQ ID NO 1 of the instantly rejected claim, the prior art of Ribot et al. does not teach all of the limitations of the claims. This argument is not persuasive because, as discussed above, instant claim 1 recites that the computer database comprises the genome sequence of (i.e. any fragment of) SEQ ID NO:1 and NOT that the computer database comprises SEQ ID NO:1. Consequently, claim 1 is interpreted such that any sequence COMPRISING a fragment of SEQ ID NO:1 meets this limitation of the instantly rejected claims.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/ Examiner, AU 1631 6 November 2009